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09/903,806	07/11/2001	Avi Ashkenazi	10466/40	1365

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EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/01/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,806

Applicant(s)

ASHKENAZI ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The preliminary amendment filed August 26, 2002 (Paper No. 9) and the preliminary amendment to the claims filed concurrently with the present application have been entered. Claims 39-44 are pending and being examined.

5

The computer readable form of the sequence listing filed December 18, 2001 (Paper No. 4) has been entered after correction of minor errors in the CRF by the Scientific and Technical Information Center staff. Specifically, the nucleic acid number "42" at the end of the nucleic line in SEQ ID NO: 173 was changed to "43".

10

According to the priority statement of August 26, 2002 (Paper No. 9), it appears that the claimed subject matter defined in the instant application is supported by the parent application PCT/US00/04414 filed February 22, 2000. Based on the information given by applicant and an inspection of the patent applications, the examiner has concluded that the subject matter defined in this application is supported by the disclosure in application PCT/US00/04414 filed February 22, 2000, but is not supported by any of the others because in order to obtain the benefit of an earlier filing date in the United States under 35 U.S.C. 120 an invention must disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States. Prior to February 22, 2000 the PRO214 polypeptide is not supported by either a specific and substantial asserted utility or a well established utility, and one skilled in the art clearly would not know how to use the claimed invention. Accordingly, the subject matter defined in claims 39-51 has an effective filing date of February 22, 2000.

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Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to February 22, 2000 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant
5 considers to have been in possession of and fully enabled for prior to February 22, 2000.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. For example, see page 69, line 8. This list is not meant to be
10 exhaustive. The lengthy specification has not been checked to the extent necessary to determine the presence of all embedded hyperlinks and/or other forms of browser-executable code. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

15 The application is not fully in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Specifically, the specification fails to recite the appropriate sequence identifiers at each place where a sequence is discussed. See page 14, line 17. This is not meant to be an exhaustive list of places where the specification fails to comply with the sequence rules. The specification
20 has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The application cannot issue until it is in compliance.

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Nucleic acid sequences with 10 or more nucleotides, at least 4 of which are specifically defined, must comply with the sequence rules. Amino acid sequences with 4 or more residues, at least 4 of which are specifically defined, must comply with the sequence rules. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For
5 example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing."

Correction is required.

Information Disclosure Statement

10 The sequences in the information disclosure statement filed March 14, 2002 (Paper No. 10) have been considered to the extent possible, but a residue by residue comparison has not been done. The "Other Art" will not be listed on any patent resulting from this application because it was not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449
15 or PTO/SB/08A and 08B form, must be filed within the set period for reply to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

20 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 is indefinite because it recites the term "specifically binds". Because the instant specification does not identify that material element or combination of elements which is unique

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to, and, therefore, definitive of "specifically binds" an artisan cannot determine what additional or material functional limitations are placed upon a claim by the presence of this element.

Claim Rejections - 35 USC § 102

5 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

10 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following rejection under 35 U.S.C. § 102 is made under the assumption that the effective filing date for the instantly claimed invention is February 22, 2000.

Claims 39-44 are rejected under 35 U.S.C. 102(a) as being anticipated by Ruben (n11).

Ruben discloses an isolated polypeptide (page 185, lines 16-17) comprising the amino acid
15 sequence of SEQ ID NO: 138 (page 59, line 29, through page 62, line 6; page 175; page 288, claim 11; pages 88-89 of the sequence listing). Ruben also discloses the signal peptide of SEQ ID NO: 138, comprising amino acids 1-26 of SEQ ID NO: 138 (page 175; page 185, line 26, through page 186, line 25). The amino acid sequence of Ruben's SEQ ID NO: 138 is 97% identical to the amino acid sequence of the polypeptide shown in Figure 40 (SEQ ID NO: 109) of
20 the present application, as indicated below:

AA76151

ID AAY76151 standard; Protein; 434 AA.

XX

25 AC AAY76151;

XX

DT 23-MAR-2000 (first entry)

XX

DE Human secreted protein encoded by gene 28.

XX

30

KW Human; secreted protein; cancer; tumour; developmental abnormality;
KW foetal deficiency; blood disorder; immune system disorder; inflammation;
KW autoimmune disease; allergy; Alzheimer's disease; cognitive disorder;
KW schizophrenia; arthritis; asthma; psoriasis; sepsis; skin disorder;

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KW atherosclerosis; diabetes; cardiovascular disorder; kidney disorder;
 KW digestive disorder; endocrine disorder; infection; AIDS; leukaemia;
 KW therapy; chromosome 3.
 5 XX
 OS Homo sapiens.
 XX
 PN WO9958660-A1.
 XX
 10 PD 18-NOV-1999.
 XX
 PF 06-MAY-1999; 99WO-US09847.
 XX
 PR 12-MAY-1998; 98US-0085093.
 15 PR 12-MAY-1998; 98US-0085094.
 PR 12-MAY-1998; 98US-0085105.
 PR 12-MAY-1998; 98US-0085180.
 PR 18-MAY-1998; 98US-0085906.
 PR 18-MAY-1998; 98US-0085920.
 20 PR 18-MAY-1998; 98US-0085921.
 PR 18-MAY-1998; 98US-0085922.
 PR 18-MAY-1998; 98US-0085923.
 PR 18-MAY-1998; 98US-0085924.
 PR 18-MAY-1998; 98US-0085928.
 25 PR 18-MAY-1998; 98US-0085925.
 PR 18-MAY-1998; 98US-0085927.
 XX
 PA (HUMA-) HUMAN GENOME SCI INC.
 XX
 30 PI Ruben SM, Florence K, Ni J, Rosen CA, Carter KC, Moore PA;
 PI Olsen HS, Shi Y, Young PE, Wei F, Brewer LA, Soppet DR;
 PI Lafleur DW, Endress GA, Ebner R;
 XX
 DR WPI; 2000-062296/05.
 35 DR N-PSDB; AAZ65277.
 XX
 PT New isolated human genes and the secreted polypeptides they encode,
 PT useful for diagnosis and treatment of e.g. cancers, neurological
 PT disorders, immune diseases, inflammation or blood disorders -
 XX
 40 PS Claim 11; Page 380-381; 475pp; English.
 XX
 CC AAZ65250 to AAZ65350 represent 97 isolated human secreted protein genes.
 CC AAY76124 to AAY76223 are the secreted proteins encoded by the 97 human
 45 CC genes. The gene encoding this protein was found to be on chromosome 3.
 CC The genes and their corresponding secreted polypeptides are
 CC useful for preventing, treating or ameliorating medical conditions,
 CC e.g. by protein or gene therapy. Also pathological conditions can be
 CC diagnosed by determining the amount of the new polypeptides in a sample
 50 CC or by determining the presence of mutations in the new genes. Specific
 CC uses are described for each of the 97 genes, based on which tissues they
 CC are most highly expressed in, and include developing products for the
 CC diagnosis or treatment of cancer, tumours, developmental abnormalities
 CC and foetal deficiencies, blood disorders, diseases of the immune system,
 55 CC autoimmune diseases, inflammation, allergies, Alzheimer's and cognitive
 CC disorders, schizophrenia, arthritis, asthma, psoriasis, sepsis, skin
 CC disorders, atherosclerosis, diabetes, cardiovascular disorders, kidney
 CC disorders, digestive/endocrine disorders, infections and AIDS. The
 CC polypeptides are also useful for identifying their binding partners.
 60 CC The sequences shown in AAY76224 to AAY76424 represent fragments of the
 CC secreted proteins.
 XX
 SQ Sequence 434 AA;
 65
 Query Match 83.8%; Score 1998; DB 21; Length 434;
 Best Local Similarity 96.6%; Pred. No. 1.2e-139;
 Matches 344; Conservative 6; Mismatches 6; Indels 0; Gaps 0;

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5 Qy 6 PKGLVPAVLWGLSLFLNLP GPIWLQSPSPPPQSPHPCHTCRGLVDSFNKGLERTIR 65
 Db 3 peglvpavlwglsflnlpgpiwlqspspppqspqphchtcrglvdsfnkgleritir 62

10 Qy 66 DNFGGGNTAWEENLSKYKDSETRIVEVLEGVCSKSDFECHRLLELSEELVESWWFHKQQ 125
 Db 63 dnfgggntaweeenlskykdsetrivevlegvcsksdfechrllelseelweswwfhkqq 122

15 Qy 126 EAPDLFQWLCSDSLKLCCPAGTFGPSCLPCPGGTERPCGGYGQCEGEGTRGGSGHCD CQA 185
 Db 123 eapdlfqwlcslslklccpagtfgpsclpcpggterpcggygqcegegrggsghcdcqa 182

20 Qy 186 GYGGEACGQCGLGYFEAERNASHLVCSACFGPCARCSGPPEESNCLQCKKGWALHHLKCVD 245
 Db 183 gyggeacgcqclgyfeaernashlvcsacfgpcarcsgpspeesnclqckkgwalhhlkcvd 242

25 Qy 246 IDECGTEGANCGADQFCVNTGEGSYECRDCAKACLGCMGAGPGRCKKCSPGYQQVGSKCLD 305
 Db 243 idecgteganccgadqfcvntegsyecrdcakaclgcmgagpgrckkcspsyqqvgskcld 302

Qy 306 VDECETEVCPGENKQCENTEGGYRCICAEGYKQMEGICVKEQIPESAGFFSEMTE 361
 Db 303 vdecetevcpgenkqcenteggyrcicaegykmegicvkeqipgafpildltpe 358.

Ruben discloses preferred epitopes of SEQ ID NO: 138 (page 61, lines 3-7) that are identical to the corresponding regions of the present application's SEQ ID NO: 109. Ruben also discloses antibodies, including monoclonal and humanized antibodies and fragments thereof (pages 196-197), as well as labeled antibodies that bind these epitopes (paragraph bridging pages 205-206 through page 206, full paragraph 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection under 35 U.S.C. § 103 is made under the assumption that the effective filing date for the instantly claimed invention is February 22, 2000.

Claims 39, 43, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koehrer (u11). Koehrer teaches a hypothetical protein that is at least 99% identical to SEQ ID NO: 109, as indicated below:

T08724
hypothetical protein DKFZp566D213.1 - human
C;Species: Homo sapiens (man)
C;Date: 11-Jun-1999 #sequence_revision 11-Jun-1999 #text_change 13-Aug-1999
C;Accession: T08724
R;Koehrer, K.; Beyer, A.; Mewes, H.W.; Gassenhuber, J.; Wiemann, S.
submitted to the Protein Sequence Database, May 1999
A;Reference number: Z16468
A;Accession: T08724
A;Molecule type: mRNA
A;Residues: 1-417 <KOE>
A;Cross-references: EMBL:AL050275
A;Experimental source: fetal kidney; clone DKFZp566D213
C;Genetics:
A;Note: DKFZp566D213.1

Query Match 98.7%; Score 2351; DB 2; Length 417;
Best Local Similarity 99.5%; Pred. No. 1.4e-150;
Matches 415; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

QY 1 MAPWPPKGLVPAVLWGLSLFLNLP GPIWLQPSPPPQSSPPPQHPCHTCRGLVDSFNKGL 60
Db 1 MAPWPPKGLVPAVLWGLSLFLNLP GPIWLQPSPPPQSSPPPQHPCHTCRGLVDSFNKGL 60

QY 61 ERTIRDNFGGGNTAWEENLSKYKDSETRLVEVLEGVCSKSDFECHRLLLELSEELVESWW 120
Db 61 ERTIRDNFGGGNTAWEENLSKYKDSETRLVEVLEGVCSKSDFECHRLLLELSEELVESWW 120

QY 121 FHKQQEAPDLFQWLCDSLKLCCPAGTFGPSCLPCPGGTERPCGGYGQCEGEGTRGGSGH 180
Db 121 FHKQQEAPDLFQWLCDSLKLCCPAGTFGPSCLPCPGGTERPCGGYGQCEGEGTRGGSGH 180

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Db 121 FHKQQGAPDLFQWLCSDSLKLCCPAGTFGPSCLPCPGGTERPCGGYGQCEGEGTRGSGH 180
 QY 181 CDCQAGYGGEACGQCGLGYFEAERNASHLVCSACFGPCARCSGPESNCLQCKKGWALHH 240
 5 Db 181 CDCQAGYGGEACGQCGLGYFEAERNASHLVCSACFGPCARCSGPESNCLQCKKGWALHH 240
 QY 241 LKCVDIDECGTEGANCGADQFCVNTGEGSYECRDCAKACLGCMGAGPGRCKKCSPGYQQVG 300
 10 Db 241 LKCVDIDECGTEGANCGADQFCVNTGEGSYECRDCAKACLGCMGAGPGRCKKCSPGYQQVG 300
 QY 301 SKCLDVDECETEVCPGENKQCENTEGGYRCICAEGYKQMEGICVKEQIPESAGFFSEMTE 360
 Db 301 SKCLDVDECETEVCPGENKQCENTEGGYRCICAEGYKQMEGICVKEQIPESAGFFSEMTE 360
 15 QY 361 DELVVLQQMFFGIIICALATLAAKGDVFTAFIFGAVAAMTGYWLSERSDRVLEGFI 417
 Db 361 DELVVLQQMFFGIIICALATLAAKGDVFTAFIFGAVAAMTGYWLSERSDRVLEGFI 417.

Koehrer does not teach an antibody that binds the hypothetical protein or a labeled
 20 antibody that binds the hypothetical protein. However, it would have been obvious to one of
 ordinary skill in the art at the time of Applicants' invention to recombinantly produce and isolate
 the hypothetical protein and make antibodies thereto, with a reasonable expectation of success.
 One of ordinary skill in the art would be motivated to make this modification so that expression
 of the hypothetical protein could be assessed or confirmed. The invention is prima facie obvious
 25 over the prior art.

Conclusion

No claims are allowable.

30 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO
 DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH
 FRIDAY FROM 7:30 A.M. TO 4:00 P.M.
 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE
 REACHED ON (703) 308-4623.
 35 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO
 THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHT FAX NUMBERS:
 BEFORE FINAL (703) 872-9306
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 IN ADDITION TO THE OFFICIAL RIGHT FAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX
 40 NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.
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 OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).
 FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.
 45 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED
 TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

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5

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
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DSR
SEPTEMBER 30, 2002